

# Easy<sup>®</sup> Line Real Time



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## Easy® KRAS cat.no. RToo1 (24 test, CE IVD)

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| <b>Main features</b>     | <p>Detection of the main mutations of exon 2 (codons 12, 13), of exon 3 (codons 59, 61) and of exon 4 (codons 117, 146) of the gene KRAS using 12 oligo mixes.</p> <p>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.</p> <p>A specific oligo control mix enables the evaluation of the quality and the quantity of the DNA in each sample.</p> |
| <b>Controls</b>          | <p>Control DNA positive for all the mutations detected by the kit.</p> <p>Reference standard DNA <b>Horizon KRAS G12V 1%</b> to monitor the analytical process and the performances of the system.</p> <p>The standard is characterized by a well defined allelic ratio wild-type/mutant.</p>  |
| <b>Sensitivity</b>       | <p>The kit allows the detection of low percentages of mutated allele in presence of high amounts of wild-type genomic DNA by real-time amplification with sequence-specific probes marked with FAM and HEX (LOD down to 0.5%)</p>  |
| <b>Starting material</b> | <p>The kit allows the analysis of DNA extracted from fresh, frozen and formalin-fixed paraffin-embedded tissues.</p>   |
| <b>Execution time</b>    | <p>2 hours</p>   |

## Easy® BRAF cat.no. RToo2 (24 test, CE IVD)

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| <b>Main features</b>     | <p>Detection of the main mutations of codon 600 of the gene BRAF using 5 oligo mixes.</p> <p>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.</p> <p>A specific oligo control mix enables the evaluation of the quality and the quantity of the DNA in each sample.</p> <p>Control DNA positive for all the mutations detected by the kit.</p> |
| <b>Controls</b>          | <p>Reference standard DNA <b>Horizon BRAF V600E 1%</b> to monitor the analytical process and the performances of the system.</p> <p>The standard is characterized by a well defined allelic ratio wild-type/mutant.</p>  |
| <b>Sensitivity</b>       | <p>The kit allows the detection of low percentages of mutated allele in presence of high amounts of wild-type genomic DNA by real-time amplification with sequence-specific probes marked with FAM and HEX (LOD down to 0.5%).</p>   |
| <b>Starting material</b> | <p>The kit allows the analysis of DNA extracted from fresh, frozen and formalin-fixed paraffin-embedded tissues.</p>   |
| <b>Execution time</b>    | <p>2 hours</p>   |

## Easy® EGFR cat.no. RToo3 (24 test, CE IVD)

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| <b>Main features</b>     | <p>Detection of the main mutations of exons 18, 19, 20, 21 of EGFR gene using 8 oligo mixes.</p> <p>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.</p> <p>A specific oligo control mix enables the evaluation of the quality and the quantity of the DNA in each sample.</p> |
| <b>Controls</b>          | <p>Control DNA positive for all the mutations detected by the kit.</p> <p>Reference standard DNA <b>Horizon EGFR ΔE746-A750 1%</b> to monitor the analytical process and the performances of the system.</p> <p>The standard is characterized by a well defined allelic ratio wild-type/mutant.</p>                                |
| <b>Sensitivity</b>       | <p>The kit allows the detection of low percentages of mutated allele in presence of high amounts of wild-type genomic DNA by real-time amplification with sequence-specific probes marked with FAM and HEX (LOD down to 0.5%).</p>   |
| <b>Starting material</b> | <p>The kit allows the analysis of DNA extracted from fresh, frozen and formalin-fixed paraffin-embedded tissues and of circulating tumor DNA extracted from plasma.</p>  |
| <b>Execution time</b>    | <p>2 hours</p>   |

## Easy® NRAS cat.no. RToo4 (24 test, CE IVD)

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| <b>Main features</b>     | Detection of the main mutations of exon 2 (codons 12, 13), of exon 3 (codons 59, 61) and of exon 4 (codons 117, 146) of NRAS gene of EGFR gene using 8 oligo mixes.<br>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.<br>A specific oligo control mix enables the evaluation of the quality and the quantity of the DNA in each sample. |
| <b>Controls</b>          | Control DNA positive for all the mutations detected by the kit.<br>Reference standard DNA <b>Horizon NRAS Q61K 1%</b> to monitor the analytical process and the performances of the system.<br>The standard is characterized by a well defined allelic ratio wild-type/mutant.  |
| <b>Sensitivity</b>       | The kit allows the detection of low percentages of mutated allele in presence of high amounts of wild-type genomic DNA by real-time amplification with sequence-specific probes marked with FAM and HEX (LOD down to 0.5%)  |
| <b>Starting material</b> | The kit allows the analysis of DNA extracted from fresh, frozen and formalin-fixed paraffin-embedded tissues.   |
| <b>Execution time</b>    | 2 hours   |

## Easy® ALK cat.no. RToo5 (24 test, CE IVD)

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| <b>Main features</b>     | Qualitative detection of aberrant expression of the tyrosin-kinase domain of ALK associated to the gene fusion by retrotranscription and co-amplification of a region located at 3' terminus of ALK mRNA (detected by a FAM marked probe) and of an endogenous control gene (detected by a HEX marked probe). |
| <b>Controls</b>          | Control RNA for the monitoring of the analytical process.   |
| <b>Starting material</b> | The kit allows the analysis of RNA extracted from fresh, frozen or formalin-fixed paraffin-embedded tissues.  |
| <b>Execution time</b>    | 2 hours   |

## Kit linea Easy®

The Easy® kits allow the qualitative detection of the main somatic mutations of the genes EGFR, KRAS, NRAS and BRAF by Real-Time PCR in association with a system of enrichment of the mutated allele.

The kit Easy® ALK is designed for the qualitative detection of the aberrant expression of the tyrosin-kinase domain of ALK, which is caused by events of gene rearrangement, by One Step Real-Time RT-PCR.

Each kit includes all the reagents necessary for the test and the positive controls of reaction. The kits are validated on the following instruments:

- Rotor-Gene Q
- Rotor-Gene 6000
- ABI 7500
- Stratagene Mx3000P
- Stratagene Mx3005P
- ABI 7300
- Bio-Rad CFX96

All the kits (on each of the above listed instruments) share the same thermal profile for the detection of the somatic mutations.

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## Helix® Circulating Nucleic Acid cat.no. H8040 (50 test, CE IVD)

The kit allows the manual extraction of circulating free DNA (cfDNA) from plasma. The kit Helix® Circulating Nucleic Acid, in association with the kit Easy® EGFR, enables the mutational analysis of EGFR gene in the circulating tumor DNA (liquid biopsy) when the tumor tissue is not evaluable, according to the EMA/129677/2014 recommendations of September 25th 2014.

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| <b>Main features</b>     | DNA capture by silica membrane and vacuum-based system.<br>System to concentrate final eluate up to 3 times included in the kit. |
| <b>Starting material</b> | 1-5 ml of fresh or frozen plasma.  |
| <b>Execution time</b>    | 3 hours  |

## Easy® DPYD cat. no. RToo6 (24 test, CE IVD)

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| <b>Main features</b>     | <p>Detection, by allelic discrimination, of the DPYD gene polymorphisms DPYD*2A (IVS14+1G&gt;A, c.1905+1G&gt;A, rs3918290), DPYD*13 (c.1679T&gt;G, rs55886062), DPYD D949V (c.2846A&gt;T, rs67376798) and DPYD IVS10 (c.1129-5923C&gt;G, rs75017182), associated with the toxicity due to the treatment with fluoropyrimidines, using 4 oligo mixes.</p> <p>Each mix allows the co-amplification of the mutant sequence (FAM) as well as the wild-type sequence (HEX).</p> |
| <b>Controls</b>          | <p>DPYD WT positive control: Positive control DNA containing a mixture of synthetic wild-type DNA sequences for DPYD polymorphisms analyzed.</p> <p>DPYD MT positive control: Positive control DNA containing a mixture of synthetic mutant DNA sequences for DPYD polymorphisms analyzed.</p>   |
| <b>Starting material</b> | The kit allows the analysis of genomic DNA extracted from whole blood  |
| <b>Execution time</b>    | 2 hours  |

## Easy® UGT1A1 cat. no. RToo7 (24 test, CE IVD)

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| <b>Main features</b>     | <p>Detection, by allelic discrimination, of the UGT1A1 gene polymorphisms UGT1A1*1 (TA)<sub>6</sub>, UGT1A1*28 (TA)<sub>7</sub>, UGT1A1*36 (TA)<sub>5</sub> and UGT1A1*37 (TA)<sub>8</sub>, associated with the toxicity due to the treatment with irinotecan, using 1 oligo mix.</p> <p>UGT1A1 mix contains HEX labeled probes for UGT1A1*28 and UGT1A1*37 and FAM labeled probes for UGT1A1*1 and UGT1A1*36.</p> |
| <b>Controls</b>          | <p>UGT1A1 WT positive control: Positive control DNA containing synthetic wild-type UGT1A1*1/*1 DNA sequence.</p> <p>UGT1A1 MT positive control: Positive control DNA containing synthetic mutant UGT1A1*28/*28 DNA sequence.</p>   |
| <b>Starting material</b> | The kit allows the analysis of genomic DNA extracted from whole blood  |
| <b>Execution time</b>    | 2 hours  |

## Easy® THYROID cat. no. RToo8 (24 test, CE IVD)

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|--------------------------|--|
| <b>Main features</b>     | <p>Detection of the main mutations of exon 2 (codons 12,13), of exon 3 (codons 61) of the genes KRAS, NRAS, HRAS and of the codons 600 and 601 of the gene BRAF using 8 oligo mixes.</p> <p>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.</p> |
| <b>Controls</b>          | Positive control DNA containing a mixture of synthetic DNA sequences that correspond to each mutation detected by this kit in a background of wild-type genomic DNA.   |
| <b>Starting material</b> | <p>The kit allows the analysis of genomic DNA extracted from fresh, frozen or formalin fixed paraffin-embedded (FFPE) tumor tissue.</p> <p>The kit allows the analysis of genomic DNA extracted from cytological samples.</p>  |
| <b>Execution time</b>    | 2 hours  |